

CLAIM AMENDMENTS

1 1. (previously presented) A pharmaceutical formulation,
2 packaged into a sachet and administered orally after dispersing in
3 water at therapeutic doses which comprises:

4 (a) alendronate microparticles coated with a polymer
5 soluble at a gastric pH of 1 to 4, but insoluble at a salivary pH
6 of 6 - 7.5, and uncoated alginic acid or sodium alginate or
7 admixtures thereof in an amount therapeutically effective to
8 prevent esophageal reflux, heartburn and esophagitis in a patient
9 taking alendronate, where

10 (b) alendronate dissolves in 900 ml 0.1 N HCl at the rate
11 of not less than 85% of within 30 minutes at the range of pH 1 - 4,

12 (c) the dispersion in a glass of 250 ml. water at the
13 degree of 25°C contains no dissolved alendronate at pH 6 - 7.5 or
14 at the most 10% w/v of alendronate dissolved in 3 minutes.

1 2. (original) The pharmaceutical formulation as claimed
2 in claim 1, comprises lubricants, diluents, flavors and sweeteners
3 or their mixture thereof.

1 3. (previously presented) The pharmaceutical formulation
2 as claimed in claim 2, where in the diluent is selected from the
3 group consisting of lactose and microcrystalline cellulose or
4 admixtures thereof.

1 4. (previously presented) The pharmaceutical formulation
2 as claimed in claim 2, where in the sweetener is selected from the
3 group consisting of aspartame, potassium acesulfame, monoammonium
4 glycyrrhizinate, sodium saccharine, sucrose and polyols, used alone
5 or in combination.

1 5. (previously presented) The pharmaceutical formulation
2 as claimed in claim 1, where in the polymer is selected from the
3 group consisting of polymethacrylates, polyvinyl acetate
4 diethylaminoacetate and poly butyl methacrylate / 2-dimethylamino-
5 ethyl methacrylate/methyl methacrylate copolymers or their mixtures
6 thereof.

1 6. (previously presented) The pharmaceutical formulation
2 as claimed in claim 1, where in the polymer is Poly(butyl
3 methacrylate, (2-dimethyl aminoethyl) methacrylate, methyl
4 methacrylate) in a ratio of 1:2:1.

1 7. (previously presented) The pharmaceutical formulation
2 as claimed in claim 1, which is dispersed in a glass of 250 ml
3 water at the degree of 25°C at pH 6 - 7.5, and which contains
4 alendronate in between 0.001% w/v - 3% w/v.

1 8. (previously presented) The pharmaceutical formulation
2 as claimed in claim 1 where in the alendronate is alendronate
3 monosodium trihydrate.

1 9. (previously presented) The pharmaceutical formulation
2 as claimed in claim 1, which is dispersed in a glass of 250 ml.
3 water at the degree of 25°C at pH 6 - 7.5, and which contains
4 uncoated alginic acid or sodium alginate or their mixtures in
5 between 0.001% w/v - 2% w/v.

1 10. (previously presented) A pharmaceutical formulation,
2 which is packaged into a sachet and orally administered after
3 dispersing in water, which comprises:
4 alendronate microparticles coated with a polymer insoluble at a
5 salivary pH 6 to 7.5, but soluble at a gastric pH of 1 to 4 wherein
6 the polymer comprises polybutyl methacrylate,
7 (2-dimethylaminoethyl)methacrylate and methyl methacrylate in a
8 1:2:1 ratio; uncoated alginic acid or sodium alginate or admixtures
9 thereof in an amount therapeutically effective to prevent
10 esophageal reflux, heartburn and esophagitis in a patient taking
11 alendronate; sucrose and sodium saccharine as sweeteners;
12 microcrystalline cellulose as diluent; and colloidal silica as a
13 lubricant, wherein the alendronate dissolves in 900 ml of 0.1N HCl
14 at a rate of not less than 85% within 30 minutes at a pH of 1 to 4,

15 and wherein the resulting dispersion in water at 25°C contains
16 either no dissolved alendronate at a pH of 6 to 7.5, or at most 10%
17 w/of dissolved alendronate after 3 minutes.

1 11. (New) A pharmaceutical formulation, packaged into a
2 sachet and administered orally after dispersing in water at
3 therapeutic doses which comprises:

4 (a) alendronate microparticles aggregated with
5 polyvinylpyrrolidone dissolved in ethanol and coated with a polymer
6 which is Poly(butyl methacrylate, (2-dimethyl aminoethyl)
7 methacrylate, methyl methacrylate) in a ratio of 1:2:1, soluble at
8 a gastric pH of 1 to 4, but insoluble at a salivary pH of 6 - 7.5,
9 said polymer in admixture with ethanol, acetone and colloidal
10 silica, and uncoated alginic acid or sodium alginate or admixtures
11 thereof in an amount therapeutically effective to prevent
12 esophageal reflux, heartburn and esophagitis in a patient taking
13 alendronate, where

14 (b) alendronate dissolves in 900 ml 0.1 N HCl at the rate
15 of not less than 85% of within 30 minutes at the range of pH 1 - 4,

16 (c) the dispersion in a glass of 250 ml. water at 25°C
17 contains no dissolved alendronate at pH 6 - 7.5 or at the most 10%
18 w/v of alendronate dissolved in 3 minutes.